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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,105	12/29/2003	Carlos Vonderwalde	R0495-01202	3163

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,105	VONDERWALDE ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-84* is/are rejected.

7)☒ Claim(s) *85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/04,2/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. **Claims (61, 62, 63, 64, 65, 72, 73), (76, 77), and (78, 79)** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims (1), (2), and (3), respectively, of U.S. Patent No. 6,929,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same invention; the application claims are merely broader in scope than the claims of U.S. 6,929,658. Regarding claim 62, claim 1 of U.S. 6,929,658 (which will be referred to as '658) claims the penetrating elements extending through the stent cover and extending over an outer surface of the stent cover. When this occurs, an inner surface of the stent (inner side of penetrating element) will be in contact with the cover. Regarding claim 63, claim 1 of '658 claims that the cover is disposed over the stent body. Regarding claim 65, the cover connectors of claim 1 of

'658 are claimed as integral with the connecting support members which are disposed between the plurality of ring sections. Therefore, there are cover connecting members that are proximate to the first and second ends of the stent. Regarding claim 73, claim 1 of '658 claims that the penetrating elements extend through the cover and over an outer surface of the stent cover. Regarding claim 79 of the instant application, claim 1 of '658 does not include the limitation that a penetrating member penetrates through both a first edge of the sheet and a second edge of the sheet. However, claim 3 of includes the limitation that penetrating elements extend through the stent cover adjacent the first edge and the second edge. If the edges overlap, a single penetrating member will penetrate both a first edge and a second edge of the sheet since it is penetrates the cover adjacent a first edge and the second edge is overlapping this first edge. The patented claims therefore anticipate the application claims.

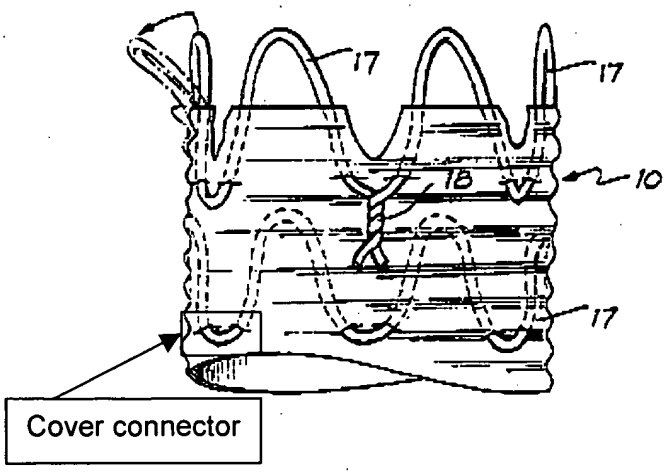
2. **Claims 66-71 and 74-75** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,929,658 in view of Hillstead (U.S. 4,856,516). Regarding claims 66, 74, and 75, claim 1 of '658 claims a plurality of ring sections having at least one connecting support member extending between adjacent rings. Regarding claim 71, these connectors can be considered elongated wall sections. As Hillstead discloses, bar members disposed substantially in parallel to the central axis of a stent body are well known in the art for connecting a plurality of ring sections. This configuration provides a high degree of flexibility. Therefore it would have been obvious to one of ordinary skill in the art to align the connecting members of claim 1 of '658 in parallel to the central axis in order to achieve this high degree of flexibility. Regarding claims 67 and 68, claim 1 of '658 claims cover connecting members integrally formed with connecting support members.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 61-65 and 72-75** are rejected under 35 U.S.C. 102(b) as being anticipated by White et al. (U.S. 5,782,904). White et al. disclose a stent assembly comprising a stent including a substantially tubular expandable stent body with walls, a first stent end, a second stent end, and a central axis, at least two cover connectors associated with the stent body, each cover connector including at least one penetrating element, and a substantially tubular stent cover (16) in contact with a surface of the stent body and secured thereto by the penetrating elements penetrating through the stent cover (see fig. 3).



5. Regarding claim 62, the stent cover is in contact with an inner surface of the stent body. The portion of (17) that is external to the graft member and forms the cover connector has an inner surface in contact with the stent cover (16).

6. Regarding claim 63, the stent cover is in contact with an outer surface of the stent body (dotted portion of 17 in fig. 6).

7. Regarding claim 64, the cover connectors are integrally formed with the stent body.

8. Regarding claim 65, White et al. disclose cover connectors proximate to both ends of the stent (see fig. 2 and 3).

9. Regarding claim 72, at least one of the cover connectors includes two penetrating elements. That is, each cover connector penetrates the cover at two points.

10. Regarding claim 73, at least a portion of at least one penetrating element penetrating through the stent cover is bent over the stent cover (see col. 5 ll. 28-32).

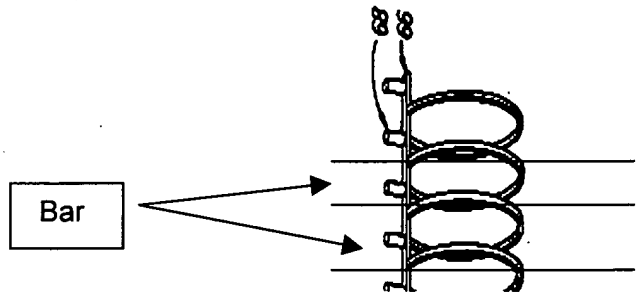
11. Regarding claims 74 and 75, the cover connectors are in line substantially parallel to the central axis (see fig. 2).

12. **Claims 61-70, 74-75, 78-82, and 84** are rejected under 35 U.S.C. 102(b) as being anticipated by Love (U.S. 5,865,723). Love discloses a stent assembly comprising a stent including a substantially tubular expandable stent body (60,62) with walls (64, 72), a first stent end, a second stent end and a central axis, at least two cover connectors associated with the stent body, each of the cover connectors including at least one penetrating element (68) and a substantially tubular stent cover (74) in contact with a surface of the stent body and secured thereto by the penetrating elements penetrating through the stent cover.

13. Regarding claims 62-65, see fig. 9.

14. Regarding claim 66, the walls of the stent body comprise bar members disposed substantially in parallel to the central axis of the stent body.

15. Regarding claims 67 and 68, a cover connector is associated with a bar member. The cover connector is integrally formed with the bar member. The examiner is considering a single bar to be the portion of (66) between a pair of adjacent rings (64). As seen below, a cover connector is associated with a bar member.



16. Regarding claims 69 and 70, the stent body comprises a plurality of ring-shaped wall sections (64) including at least one bar member extending between any two adjacent wall sections.

17. Regarding claims 74 and 75, the cover connectors are in line substantially parallel to the central axis.

18. Regarding claims 78 and 79, the stent cover is substantially a sheet in contact with a surface of the stent body so that a first edge and a second edge of the sheet overlap. The penetrating elements penetrate through both edges of the sheet where they overlap (see fig. 9).

19. Regarding claim 80, Love discloses a method of making a stent assembly comprising the steps of providing a stent including a substantially tubular stent body (60, 62) with a first stent end, a second stent end and at least two cover connectors associated with the stent body, each cover connector including at least one penetrating element, contacting a sheet of material with a surface of the stent body so that a first edge of the sheet is in proximity of a second edge of the sheet so as to form a substantially tubular stent cover and piercing the sheet with the penetrating elements so that the penetrating elements penetrate through the sheet so as to

secure the sheet to the stent (col. 8 ll. 32-50). The cover connectors penetrate the plane of the sheet.

20. Regarding claims 81, 82, and 84, see fig. 9.

21. **Claims 61-64, 66-68, and 71** are rejected under 35 U.S.C. 102(b) as being anticipated by Song (U.S. 5,330,500). Song discloses a stent assembly comprising a stent including a substantially tubular expandable stent body (10) with walls, a first stent end, a second stent end and a central axis, at least two cover connectors (41, 43) associated with the stent body, each of the cover connectors including at least one penetrating element (411) and a substantially tubular stent cover (91) in contact with a surface of the stent body and secured thereto by the penetrating elements penetrating through the stent cover.

22. Regarding claims 62 and 63, see col. 3 ll. 43-45.

23. Regarding claims 64, the cover connector is integrally formed with the stent body (see fig. 3).

24. Regarding claims 66-68, the cover connectors (411) are integrally formed with bar members (41 and 43) that are disposed substantially in parallel to the central axis of the stent body (see fig. 3).

25. Regarding claim 71, the stent body further comprises a plurality of elongated wall sections (31, 35) disposed substantially in parallel to the central axis.

26. **Claims 61-65 and 76** are rejected under 35 U.S.C. 102(e) as being anticipated by Edwin et al. (U.S. 6,053,943). Edwin et al. discloses a stent assembly comprising a stent including a substantially tubular expandable stent body (122) with walls, a first stent end, a second stent end and a central axis, at least two cover connectors (62) associated with the stent body, each of the cover connectors including at least one penetrating element (end of 62) and a

substantially tubular stent cover (120) in contact with a surface of the stent body and secured thereto by the penetrating elements penetrating through the stent cover.

27. Regarding claims 62-65, see fig. 9b, col. 10 ll. 8-33, and col. 14 ll. 14-25.

28. Regarding claims 74 and 75, the cover connectors are in line substantially parallel to the central axis (see fig. 9b).

29. Regarding claim 76, the sheet is brought into contact with the stent body such that first and second edges of the sheet substantially abut each other (col. 13, ll. 3-8).

30. **Claims 80-82** are rejected under 35 U.S.C. 102(b) as being anticipated by Buirge et al. (U.S. 5,693,085). Buirge et al. discloses a method of making a stent assembly including the steps of providing a stent including a substantially tubular stent having a first and second end and at least two cover connectors associated with the stent body, each of the cover connectors including at least one penetrating element (col. 11, ll. 30-35), contacting graft material with the surface of the stent so that a first edge of the sheet is in proximity of a second edge of the sheet so as to form a tubular stent cover (see fig. 18 and col. 12 ll. 29-34), and piercing the graft with the penetrating elements so that the elements penetrate through the graft so as to secure the graft to the stent.

31. Regarding claim 81, the sheet may be folded such that it is in contact with an inner surface of the stent body (see fig. 14).

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

33. **Claim 77** is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwin et al. Edwin et al. discloses the invention substantially as stated above but fails to disclose that a cover connector has two penetrating elements, a first penetrating element penetrating through the stent cover proximately to the first edge of the sheet and a second penetrating element penetrating through the stent cover proximately to the second edge of the sheet. Edwin et al. does not expressly disclose that the connector members having two penetrating members, one being proximate to a first edge of the stent cover and the other being proximate to a second edge of the stent cover. However, looking at fig. 3B of Edwin et al., the examiner is considering a connecting member to be the portion of the stent that includes the two central barbs (64) and the connecting piece. Edwin et al. further discloses that the edges of the stent cover are brought into proximity to each other such that they abut each other (col. 13, ll. 4-7). It would have been obvious to one of ordinary skill in the art to modify the device of Edwin et al. to have the penetrating members of the cover connectors spaced such that one penetrating member is proximate to one edge of the sheet and the other penetrating member is proximate to the other edge of the sheet because these barbs are located all the way around the device to help anchor the device. The point where the sheet edges abut will have penetrating members on either side of it, with a connecting portion of the connecting member there between.

34. **Claim 83** is rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. (U.S. 5,693,085) in view of White (U.S. 5,782,904). Buirge et al. discloses the method substantially as stated above, but fails to expressly disclose bending a portion of the penetrating elements penetrating through the sheet over the sheet.

35. However, White et al. discloses that it is old and well known in the art to bend penetrating members used to connect a graft to a stent in order to have penetrating members project in opposite longitudinal directions along the graft body. This assists in preventing

longitudinal movement of the graft along the vessel in either direction (col. 3 ll. 55-61). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Buirge et al. to include the step of bending a portion of the penetrating elements penetrating through the sheet over the sheet as made obvious by White et al. in order to gain the advantage of preventing longitudinal movement of the graft along the vessel in either direction.

36. **Claim 84** is rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. (U.S. 5,693,085) in view of Love (U.S. 5,865,723). Buirge et al. discloses the method substantially as stated above, but fails to expressly disclose that the ends of the sheet overlap and the penetrating elements penetrate through the overlapping sheet edges.

37. However, Love discloses that it is old and well known in the art to overlap the edges of a graft sheet in order to prevent leakage from the site where the two edges of the graft are connected (col. 7 ll. 5-10). Furthermore, Love discloses that penetrating members placed where the sheet edges overlap can be used to enhance the connection between the edges (col. 8 ll. 38-50 and fig. 9). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Buirge et al. to include overlapping edges on the graft such that a penetrating element penetrates through the overlapping edges as made obvious by Love in order to gain the advantage of a better connection between the graft edges.

Allowable Subject Matter

38. **Claim 85** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. 5,755,778 to Kleshinski discloses a stent with penetrating members which penetrate a graft covering the stent and U.S. 5,397,355 to Marin et al. discloses a stent with penetrating members which can be used to connect a graft to a stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 1/10/07

GLENN K. DAWSON
PRIMARY EXAMINER